

**EXHIBIT 4-a to PLAINTIFFS’
APPENDIX OF EXPERT REPORTS**

Expert Report of James Geldhof
Based Upon Review as of August 3, 2020

I. Experience and Training

I graduated in 1972 from Eastern Michigan University with a Bachelor of Business Administration. I was hired by the Drug Enforcement Administration in 1972 and completed Basic Diversion Investigator School. I spent more than 40 years employed by the DEA and retired from there in 2016.

From June 1972 through August of 1974, I was a DEA Diversion Investigator out of Detroit, Michigan during which I conducted a full range of investigations of DEA registrants. I was responsible as lead investigator for the prosecution of the Vice President of a local pharmaceutical company and the subsequent revocation of the company's DEA license. I also met with and spoke to various pharmaceutical companies regarding their responsibilities under the Controlled Substances Act.

Effective August of 1974, I was promoted to DEA Staff Assistant in Washington, DC where I was responsible for coordinating investigative efforts over six divisions. My responsibilities included personnel support, policy interpretations, funding and liaison with other components of DEA Headquarters, and liaison between field and headquarters within the Diversion Program. I prepared the Diversion Control Budget for the entire Diversion Program. I initiated division evaluation programs to assist in staffing personnel. While not on staff, I also taught classes at the DEA's Training Academy on a number of different topics.

In June 1978, I became the DEA Diversion Group Supervisor in New York, New York office. I moved to the Newark, New Jersey office in July 1979 where I stayed until I moved back to the Detroit, Michigan office in July 1986. As a DEA Diversion Group Supervisor, I supervised the Diversion Groups in the cities I identified. My Groups were tasked with investigations of regulatory, criminal, civil and administrative cases aimed at preventing diversion of controlled substances. Under my supervision, my Groups' investigations resulted in regulatory, criminal, civil and administrative actions taken against those responsible for violating the laws and regulations governing the manufacture, distribution, prescribing and dispensing of controlled substances.

In July 2005, I became Acting DEA Diversion Program Manager and was made permanent Diversion Program Manager in October 2005 in the Detroit, Michigan office. As Diversion Program Manager, I was responsible for oversight of Diversion Groups throughout Michigan, Ohio and Kentucky. I was responsible for oversight of investigations, personnel, budget control, and I was a liaison to a number of other state and federal agencies. Among the many enforcement actions, I participated in were Harvard Drug, KeySource Pharmaceutical, Masters Pharmaceutical, McKesson, Miami-Luken and Mallinckrodt. I also represented the DEA in any number of meetings with law enforcement and professional and community groups. I remained in this position until I retired from the DEA in January 2016.

Throughout my tenure at the DEA, I participated in and completed a number of training programs, conferences and seminars addressing the laws and regulations and the enforcement of the laws and regulations governing the manufacture, distribution, dispensing and prescribing of

controlled substances. I also qualified for and obtained Top Secret Security Clearance. Additionally, I received numerous awards and commendations for my performance throughout the years.

Since my retirement in 2016, I have used my knowledge, experience and training in a number of consulting roles. I have been hired by members of the pharmaceutical and health care industries to evaluate and assess their compliance with the laws and regulations governing the handling of controlled substances under the Controlled Substances Act. I have testified by deposition once in the last four years as an expert in *Staubus et al. v Purdue Pharma, L.P.*, et al., Case No. C41916, Circuit Court for Sullivan County, Tennessee. I am unaware of any time that my opinions were limited or stricken by a court.

I have been retained as a consultant in this matter and intend to provide my opinions regarding the history of the laws and regulations governing the pharmaceutical industry and the enforcement by the DEA of the laws and regulations as they apply to distributors. I am paid \$300.00 per hour to review documents, communicate with counsel, and for any time spent testifying whether in deposition or before the court.

Based upon my extensive training, knowledge and experience, I am familiar with the legal and regulatory framework that exists governing the manufacture, dispensing, prescribing and distribution of controlled substances. I am also familiar with the enforcement mechanisms available to the State and Federal agencies to enforce the governing laws and regulations.

II. Laws and Regulations

In 1970, Congress passed the Comprehensive Drug Abuse Prevention and Control Act.¹ Title II of the Act contains the enforcement provisions and is known as The Controlled Substances Act (“CSA”). 21 USC ss 801-971. The Drug Enforcement Administration (“DEA”) was created by President Nixon in 1973 as part of a reorganization of the many agencies involved at the time in the enforcement of the laws and regulations governing controlled substances. The DEA was placed under the authority of the Department of Justice.² The reason for the CSA is stated in the Act itself: “The illegal importation, manufacture, distribution and possession and improper use of controlled substances have a substantial and detrimental effect on the health and general welfare of the American People.” 28 USC s 801(2) (2006). Each distributor owes a duty to ***maintain effective control*** against diversion of prescription opiates into the illicit market.³

The Controlled Substances Act and the regulations that implement the CSA create restrictions on the manufacturing, distributing, prescribing and dispensing of certain substances and chemicals. There are five schedules into which the regulated drugs, substances and chemicals

¹ 84 STAT Public Law 91-513 (Oct. 27, 1970).

² <https://www.dea.gov/sites/default/files/2018-07/Early%20Years%20p%2012-29%20%281%29.pdf>

³ 21 U.S.C. § 823(b)(1) (1970) (*emphasis added*.)

are divided based on a number of criteria. Those placed in Schedule V are the least likely to be abused. As the Schedule number decreases, the potential for abuse increases.⁴ Opioids and opiates are defined as “narcotic drugs” under the CSA.⁵

The laws applicable to manufacturers and distributors of controlled substances actually predate the 1970 legislative act. As early as 1943, the United States Supreme Court reviewed the trial and resulting conviction of a company distributing controlled substances to a physician that was known to supply morphine sulfate illegally.⁶ The Supreme Court even then stated, “Additional facts, such as quantity sales, high pressure sales methods, abnormal increases in the size of the buyer’s purchases, etc., which would be wholly innocuous or not more than ground for suspicion in relation to unrestricted goods, may furnish conclusive evidence, in respect to restricted articles, that the seller knows the buyer has an illegal object and enterprise.”⁷ Identification of orders that raise suspicion of diversion followed by action to prevent diversion in the form of reporting and ceasing shipments is in my experience the core of the responsibilities placed on companies licensed to distribute controlled substances.

Based upon my education, training and experience, the DEA’s enforcement role included inspection, oversight, and when necessary, initiation of license revocation or suspension as well as the use of other enforcement remedies of a manufacturer or distributor that was violating the laws and/or regulations. The Code specifically required that all manufacturers or distributors of controlled substances have to register with the Attorney General.⁸ The implementing regulations mandate that the registrant

shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.⁹

These provisions existed prior to my employment with the DEA in 1972.

⁴ 21 USC 812(a) and (b).

⁵ 21 USC 802 (17).

⁶ *Direct Sales, Co v. U.S.*, 319 U.S. 703 (1943) CAH_MDL_PRIORPROD_DEA07_01178176_R

⁷ *Id.* at CAH_MDL_PRIORPROD_DEA07_01178179_R

⁸ See 28 USC § 823.

⁹ 21 CFR 1301.74(b).

III. Oversight

In my experience, the DEA uses Investigators to engage in oversight of the industry, including manufacturers and distributors. The investigators' conduct is governed by the DEA Diversion Investigator's Manual.¹⁰ Among the avenues available to the Investigators are on-site inspections, record reviews and access to the self-reporting information mandated by federal law.

As a result of the 1970 Comprehensive Drug Abuse Prevention and Control Act, the Automation of Reports and Consolidated Orders System/Diversion Analysis and Detection System ("ARCOS/DADS") was created. The DEA defines ARCOS as follows: "The Automation of Reports and Consolidated Orders System (ARCOS) is the automated system developed by DEA to monitor selected controlled substances. ARCOS software enables the government to maintain a current and historical record of selected controlled substance inventories and transactions from the point of manufacture to the point of sale, distribution, or other disposition, and finally, to the dispensing (consumption) level."¹¹ Based upon my training, education and experience, the Defendants are among those required to report the raw data available to them regarding all transactions involving Schedule I, II and III narcotic controlled substances. Opioids and opiates are among the Schedule II and III narcotics for which all transaction data must be reported for inclusion in ARCOS/DADS.

During my decades long career in DEA Diversion Program, an overarching responsibility was to ensure that distributors such as Defendants maintained effective controls to prevent diversion and to monitor for suspicious orders, stop shipments of suspicious orders and report the suspicious orders to the DEA. Since before my employment with the DEA, the regulations regarding suspicious orders stated:

The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.¹²

From time to time throughout the years the DEA provided written explanations of the laws and regulations governing the manufacture, distribution, prescribing and dispensing of controlled substances. The written explanations took many forms, including, among other things, manuals issued to the DEA investigators and letters to the distributors. The DEA Diversion Investigator's Manual dating back to at least 1996 specifically stated that: 1) "Registrants are required to inform DEA of suspicious orders", "Registrants, who routinely report suspicious orders, yet fill these orders, with reason to believe they are destined for the illicit market, are expressing an attitude of irresponsibility that is a detriment to the public health and safety as set forth in 21 U.S.C. 823 and

¹⁰ See generally, CAH_MDL_PRIORPROD_DEA07_01176247; CAH_MDL2804_02145395.

¹¹ <https://www.deadiversion.usdoj.gov/arcos/handbook/section1.htm>.

¹² 21 CFR 1301.74(b).

824;” and 3) orders with characteristics leading to possible diversion include “orders of unusual size, unusual frequency, or those deviating substantially from a normal pattern.”¹³

In 2005, the DEA created the Distributor Initiative Program for the specific purpose of “educat[ing] registrants on maintaining effective controls against diversion, and monitoring for and reporting suspicious orders.”¹⁴ I am also aware of meetings held with each of the Defendants in late 2005 and early 2006. The purpose of the meetings was to address each Defendants’ role in identifying suspicious orders with emphasis on internet pharmacies. The meetings included a power point presentation by DEA representatives which specifically reviewed the statutes, regulations, enforcement actions and even court decisions addressing the Defendants’ obligations to monitor, identify and report suspicious orders as well as their obligation to cease shipments when an order appeared suspicious unless and until a complete investigation dispelled any suspicions. The DEA provided detailed examples of conduct and orders that should alert the Defendants to the likelihood of or at least potential for diversion.¹⁵

Following the Distributor Initiative Briefings, based upon my experience, there was still Administration-wide concern over the distributors’ failure to comply with their legal monitoring and reporting obligations. To address this concern, DEA Deputy Assistant Administrator Joseph Rannazzisi sent a September 27, 2006 Guidance Letter to all distributors and identified the purpose of the letter was “to reiterate the responsibilities of controlled substance distributors in view of the prescription drug abuse problem our nation currently faces.”¹⁶ The letter detailed specific statutes and regulations with which the distributors were required to comply. Deputy Assistant Administrator Rannazzisi even highlighted the fact that the distributors’ suspicious order reporting obligations were separate from and in addition to the distributors’ obligations to monitor for suspicious orders. “It bears emphasis that the foregoing [suspicious order reporting obligations under 21 CFR 1301.74(b)] reporting requirement is in addition to, and not in lieu of, the general requirement under 21 USC 823(e) that a distributor maintain effective controls against diversion.”¹⁷ The September 2006 Guidance Letter was very clear in its reminder of the distributors’ obligations to monitor for and prevent diversion of controlled substances: “Again, to maintain effective controls against diversion as section 823(e) requires, the distributor should exercise due care in confirming the legitimacy of all orders prior to filling.”¹⁸ The Letter goes on to make clear that the suspicious order reporting requirements are also in addition to the ARCOS transactional data reporting requirements set forth in 21 CFR 1304.33. The Guidance Letter included a full page of characteristics and circumstances that should give rise to treating an order as suspicious. The same letter was resent on February 7, 2007 to the distributors.

¹³ CAH_MDL2804_02203353 @ 56-57

¹⁴ <https://www.drugcaucus.senate.gov/sites/default/files/Rannazzisi%20Testimony.pdf>.

¹⁵ US-DEA-00000147; ABDCMDL00315887; US-DEA-00000352; CAH_MDL2804_01457737; US-DEA-00000369; MCKMDL00496859.

¹⁶ See, e.g., ABDCMDL00269683 at 85 & 87; CAH_MDL2804_00061280 at 86 - 87; MCKMDL00478906-07.

¹⁷ ABDCMDL00269683 at 88.

¹⁸ *Id.*

Deputy Assistant Administrator Rannazzisi sent a December 27, 2007 Guidance Letter to all manufacturers and distributors of controlled substances: “The purpose of this letter is to reiterate the responsibilities of controlled substance manufacturers and distributors to inform DEA of suspicious orders in accordance with 21 CFR 1301.74(b).”¹⁹ The letter continued:

Registrants are reminded that their responsibility does not end merely with the filing of a suspicious order report. Registrants must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels.²⁰

The Guidance Letter states unequivocally that “excessive purchases” reporting does not satisfy “suspicious order reports” filing obligations.²¹ The Guidance Letter also specifically directed manufacturers and distributors to the Southwood Pharmaceuticals Final Order issued by the DEA for additional information and guidance in the manufacturers and distributors “obligation to maintain effective controls against diversion of controlled substances.”²²

IV. Enforcement

The DEA uses criminal and administrative processes to enforce the laws and regulations governing the manufacture and distribution of controlled substances. The DEA posts information about enforcement proceedings on its website for anyone to see and often issues press releases about the enforcement proceedings which allows registrants that were not part of the enforcement or administrative action to be aware of the type of conduct the DEA deems actionable.

The Final Order referenced in the December 2007 Guidance Letter from Rannazzisi was a DEA Order against Southwood Pharmaceuticals which upheld a license revocation issued in November 2006 for repeatedly supplying hydrocodone to pharmacies where the orders were unusual in size, frequency and pattern but were not reported to the DEA as suspicious orders.

Over the next several years, the DEA continued enforcement and administrative actions. Some of the actions taken by DEA are listed below and while not exhaustive, they are indicative of the types of actions DEA took against distributors specifically.

- April 24, 2007: Order to Show Cause and Immediate Suspension Order against the AmerisourceBergen Orlando, Florida distribution center alleging failure to maintain effective controls against diversion of controlled substances.²³

¹⁹ *Id.* at 85. *See also*, CAH_MDL2804_00061280-81; MCKMDL00478910-11.

²⁰ *Id.*

²¹ *Id.* at 86.

²² *Id.*

²³ <https://investor.amerisourcebergen.com/news/news-details/2007/AmerisourceBergen-Signs-Agreement-with-DEA-Leading-to-Reinstatement-of-Its-Orlando-Distribution-Centers-Suspended-License-to-Distribute-Controlled-Substances/default.aspx>.

- June 22, 2007: AmerisourceBergen entered into a settlement and release agreement with the DEA related to the allegations made by the agency.²⁴
- November 29, 2007: Order to Show Cause and Immediate Suspension Order against the Cardinal Health Auburn, Washington Distribution Center which suspended their DEA registration for failure to maintain effective controls against diversion.²⁵
- December 7, 2007: Order to Show Cause and Immediate Suspension Order against the Cardinal Health Lakeland, Florida Distribution Center for failure to maintain effective controls against diversion.²⁶
- December 7, 2007: Order to Show Cause and Immediate Suspension Order against the Cardinal Health Swedesboro, New Jersey Distribution Center for failure to maintain effective controls against diversion.²⁷
- January 30, 2008: Order to Show Cause against the Cardinal Health Stafford, Texas Distribution Center for failure to maintain effective controls against diversion. Cardinal voluntarily suspends shipments of any controlled substances from the location pending resolution of allegations.²⁸
- May 2, 2008: McKesson Corporation agrees to \$13 million civil penalty enters into an Administrative MOA with the DEA. MOA provides that McKesson agrees to “maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 C.F.R. § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program.”²⁹
- On September 30, 2008: Cardinal agrees to a \$34 million civil penalty enters into a Settlement and Release Agreement and Administrative Memorandum of Agreement (MOA) with the DEA for failure to maintain effective controls against the diversion of controlled substances at enumerated distribution centers.³⁰

²⁴ *Id.*

²⁵ <https://ir.cardinalhealth.com/news/press-release-details/2007/Cardinal-Health-Receives-DEA-Order-to-Temporarily-Cease-Distribution-of-Controlled-Substances-from-Auburn-Wash-Facility/default.aspx>.

²⁶ <https://cardinalhealth.mediaroom.com/newsreleasearchive?item=122500>.

²⁷ CAH_MDL_PRIORPROD_DEA12_00013049.

²⁸ CAH_MDL_PRIORPROD_DEA12_00004212.

²⁹ https://www.dea.gov/sites/default/files/2018-06/Pharmaceutical%20Agreements%20-%20McKesson%20-%202008_0.pdf

³⁰ https://www.justice.gov/archive/usao/co/news/2008/October08/10_2_08.html.

- April 21, 2009: Settlement and Release Agreement and Administrative Memorandum of Agreement between DOJ/DEA and Masters Pharmaceutical Inc.³¹
- June 15, 2010: Order to Show Cause and Immediate Suspension Order served on The Harvard Drug Group, Livonia, MI.³²
- June 10, 2010: Suspension of Sunrise Wholesale, Inc. from selling controlled substances for supplying excessive amounts of oxycodone.³³
- April 18, 2011: Harvard Drug Group agrees to \$8,000,000 in civil penalties, settles with DEA regarding allegations that Harvard failed to have effective system for identifying suspicious orders.³⁴
- June 10, 2011: Order to Show Cause and Immediate Suspension Order Keysource Medical Inc. for distribution oxycodone to Florida.³⁵
- February 2, 2012: Order to Show Cause and Immediate Suspension Order Cardinal Health Lakeland, Florida Distribution Center for failure to maintain effective controls against diversion.³⁶
- March 7, 2012: Memorandum of Opinion from the United States District Court for the District of Columbia, *Cardinal Health, Inc., vs. Eric H. Holder, Jr.*, Civil Action No. 12-185 (RBW), denying Cardinal's challenge of the DEA's Order to Show Cause and Immediate Suspension of Registration of Cardinal's Lakeland Distribution Center.³⁷
- May 14, 2012: Cardinal Health Administrative MOA with the DEA, stipulates that its compliance with the terms of the 2008 MOA were inadequate and suspends Lakeland Distribution Center DEA registration for two years.³⁸

³¹ <https://www.dea.gov/sites/default/files/2018-06/Pharmaceutical%20Agreements%20-%20Masters%20Pharmaceutical%20-%202009.pdf>.

³² <https://www.dea.gov/sites/default/files/2018-06/Pharmaceutical%20Agreements%20-%20Harvard%20Drug%20Group%20-%202011.pdf>.

³³ <https://www.sun-sentinel.com/business/fl-xpm-2010-06-22-fl-drug-wholesaler-stopped-20100621-story.html>.

³⁴ <https://www.dea.gov/press-releases/2011/04/18/michigan-based-pharmaceutical-wholesaler-harvard-drug-group-pay-us>.

³⁵ <https://www.dea.gov/press-releases/2011/06/10/cincinnati-pharmaceutical-suppliers-dea-license-suspended>.

³⁶ CAH_MDL2804_02465982.

³⁷ https://www.govinfo.gov/content/pkg/USCOURTS-dcd-1_12-cv-00185/pdf/USCOURTS-dcd-1_12-cv-00185-0.pdf.

³⁸ CAH_MDL2804_02465982.

- September 8, 2015: Masters Pharmaceutical – DEA Acting Administrator Chuck Rosenberg Final Order revoking the DEA registration of Master Pharmaceutical Inc.³⁹
- December 22, 2016: Consent Order between the United States and Kinray, LLC, a subsidiary of Cardinal Health.⁴⁰
- December 23, 2016: Cardinal Health agrees to pay \$34 million civil penalty regarding allegations it failed to report suspicious orders and meet its obligation under the CSA in Florida, Maryland, New York, and Washington.⁴¹
- January 5, 2017: McKesson Administrative MOA with the DEA, agrees to pay \$150 million civil penalty for violation of the 2008 MOA and failure to identify and report suspicious orders at numerous distribution centers.⁴²
- June 30, 2017: United States Court of Appeals for the District of Columbia Circuit published opinion denying the Masters’ petition of review and upholding the Final Order.⁴³

Congress became interested in the distribution of opioids in West Virginia in particular apparently after articles appeared in the news media in 2017.⁴⁴ In 2018, the Energy and Commerce Committee held hearings at which representatives of five distributors answered questions under oath. Among those providing sworn testimony were George S Barrett, Executive Chairman of the Board, Cardinal Health, Inc.; Steven H. Collis, Chairman, President and CEO, AmerisourceBergen Corp.; and John H. Hammergren, Chairman, President and CEO, McKesson Corp.⁴⁵ Mr. Barrett, Mr. Collis and Mr. Hammergren each testified generally that they would exercise better judgment today than they did previously.⁴⁶ In addition to the sworn testimony of the Defendants’ highest officers, the Committee engaged in an investigation into the Defendants’ compliance programs and shipments to areas in West Virginia.⁴⁷ The Committee described the Defendants’ conduct and lack of compliance as “astonishing and concerning.”⁴⁸

³⁹ *Masters Pharm., Inc.*, 80 Fed. Reg. 55,418-55,501 (Drug Enf’t Admin. Sept. 15, 2015).

⁴⁰ <https://www.justice.gov/usao-sdny/press-release/file/920806/download>.

⁴¹ <https://www.justice.gov/usao-mdfl/pr/united-states-reaches-34-million-settlement-cardinal-health-civil-penalties-under>.

⁴² <https://www.justice.gov/opa/pr/mckesson-agrees-pay-record-150-million-settlement-failure-report-suspicious-orders>.

⁴³ *Masters Pharm., Inc. v. Drug Enf’t Admin.*, 861 F.3d 206 (D.C. Cir. 2017).

⁴⁴ *Red Flags and Warning Signs Ignored: Opioid Distribution and Enforcement Concerns in West Virginia*, Energy and Commerce Committee Majority Staff (Dec. 19, 2018).

⁴⁵ *Id.* at 102-103.

⁴⁶ *Id.*

⁴⁷ *Id.* at 105

⁴⁸ *Id.*

Pursuant to 28 U.S.C. § 1746, I declare, to the best of my knowledge, under penalty of perjury that the foregoing is true and correct.

Signed by,



James Geldhof

Executed on:

8/3/2020